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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,103	01/23/2002	Lydia L. Sohn	PRINP002	9457

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BEYER WEAVER & THOMAS LLP
P.O. BOX 778
BERKELEY, CA 94704-0778

EXAMINER
LAIR, DONALD M

ART UNIT	PAPER NUMBER
2858	

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/056,103	SOHN ET AL.	
	Examiner	Art Unit	
	Donald M. Lair	2858	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claim 38 remains withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected method of making, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1 – 5 and 8 – 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta (US-6,426,615) in view of Kricka et al. (US-5,744,366).

4. In regards to Claims 1, 3, 4, 29, and 37, Mehta discloses a device for sensing and characterizing particles by the Coulter principle, the apparatus comprising:

a conduit through which a liquid suspension of particles to be sensed and characterized can be made to pass, wherein the conduit has an effective electrical impedance which is changed with the passage of each particle therethrough and wherein the conduit has a cross-sectional area of less than about 1 μm^2 (Abstract; Column 1, lines 58 – 61);

a liquid-handling system for causing the liquid suspension of particles to pass through the conduit (Column 1, lines 20 – 33; Column 8, lines 51 – 59); and

a measurement system for sensing the change of electrical impedance in the conduit (Column 1, lines 20 – 33). The Mehta reference fails to disclose the length of the conduit.

5. Krica et al. disclose a device for characterizing particles wherein the length of the conduit may be from 0.1 to 1,000 μm (Kricka et al.: Column 8, lines 49 – 58).

6. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention disclosed by Mehta by manufacturing the conduit with a length between 0.1 and 1,000 μm as taught by Kricka et al., since discovering or selecting optimum length would be within the level of ordinary skill in the art.

7. In regards to Claim 2, Mehta discloses a device comprising the elements described above, wherein the liquid handling system comprises two reservoirs linked by the conduit (Column 1, lines 24 – 27).

8. In regards to Claims 5 and 31, Mehta discloses a device comprising the elements described above, further comprising a microfluidics system for delivering the liquid suspension of particles to the liquid handling system (Figs. 1, 3, 5, and 7; Column 1, lines 20 – 33).

9. In regards to Claims 10 and 36, Mehta discloses a device comprising the elements described above, wherein the measurement system comprises a four-point electrode system (Mehta: Column 11, lines 34 – 50; Claim 1).

10. In regards to Claims 8, 9, 11 – 22, 24 – 28, and 32 – 35, Mehta discloses a device comprising the elements described above, but fails to teach forming the conduit at least in part by an elastomeric material.

11. Kricka teaches forming the conduit at least in part by an elastomeric material (Column 9, lines 17 – 25).

12. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention taught by Mehta to use elastomeric material when forming the conduit for the purpose of enabling a transparent embodiment for use with an optical detection system (Column 9, lines 21 – 25).

13. In regards to Claims 23 and 30, Mehta discloses a device comprising the elements described above, but fails to disclose measuring the particle's residence time in the conduit.

14. Kricka et al. disclose measuring the particle's residence time in the conduit (Column 9, lines 45 – 48; Claim 11).

15. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention disclosed by Mehta to measure the residence time of the particle in the conduit as disclosed by Kricka et al. for the purpose of obtaining more detailed information about the flow rate and behavior of the particles.

16. Claim 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta (US-6,426,615) in view of Kricka et al. (US-5,744,366), as applied to Claim 1, and in further view of Anderson et al. (US-6,168,948).

17. In regards to Claims 6 and 7, Mehta discloses a device comprising the elements described above, but fails to disclose functionalizing the surface of the conduit / reservoirs to reduce or enhance adsorption of the particles to the surface.

18. Anderson et al. disclose a system for genetic analysis wherein the surface of the conduit and reservoirs have been functionalized to reduce or enhance adsorption of the particles to the surface (Column 55, lines 27 and 28).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device disclosed by Mehta in view of Kricka et al. by functionalizing the surface of the conduit / reservoirs as taught by Anderson et al. for the purpose of assisting the sample flowing through the device to reach equilibrium.

Response to Arguments

19. Applicant's arguments filed 03/04/04 have been fully considered but they are not persuasive.

20. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

21. In this case, Mehta teaches that the aperture size must be appropriately chosen "such that the majority of particles preferably lie within 2% to 60% of the aperture diameter" (Column 8, lines 11 – 14) and that "a long aperture is desirable because it smooths out turbulence and other non-linearity affecting the cell movements before readings are taken" (Column 15, lines 5 – 8). Kricka et al. also teach that the aperture, or flow channel, size must be chosen appropriately for the particle size that will be passing through the aperture (Column 8, line 49 – Column 9, line 8)

and in particular teach "at least one of the chambers and/or flow channels of the device has a mesoscale dimension, i.e., at least one cross-sectional dimension on the order of 0.1 to 1,000 micrometers" (Column 8, lines 49 – 51).

22. The Applicant suggests that the combination is improper because Mehta "aims to impede the movement of particles from one liquid container to another…" while in Kricka "fluid flow properties in the device should neither impede nor enhance the movement of cells within the flow channel."

23. The Examiner disagrees with the Applicant's stance that Mehta impedes the flow of fluid through the channel. The Applicant appears to be interpreting the phrase "constricted electrical path" to mean that the Mehta reference teaches constricting the flow of fluid through the channel. The Examiner asserts that this is an invalid interpretation in view of the fact that Mehta defines "constricted electrical path" as "a volume between a pair of active electrodes in which a substantial current is established between the electrodes, the related electric field being substantially restricted to the constricted electrical path" (Column 6, lines 27 – 31). The physical flow of fluid through the conduit is not mentioned at all. Further, the Examiner believes that Mehta does not teach, or even suggest, impeding the flow of fluid through the conduit anywhere in the disclosure.

24. Since Mehta does not require the flow of fluid through the aperture to be impeded, and in fact states that a long aperture is desirable to "get good flow characteristics" (Column 15, lines 1 – 8) and Kricka teaches using a flow channel with a "cross-sectional dimension on the order of 0.1 to 1,000 micrometers" to promote natural flow characteristics it is clear that combination of Kricka with Mehta would not defeat the intended purpose of the device of Mehta.

25. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

26. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donald M. Lair whose telephone number is (571) 272-2232. The examiner can normally be reached on Monday - Friday, 8 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, N. Le can be reached on (571) 272-2233. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Donald M. Lair
Patent Examiner
Art Unit 2858
May 25, 2004

N. Le
Supervisory Patent Examiner
Technology Center 2800